Citation:

de Luis DA, Sagrado MG, Conde R, Aller R, Izaola O. The effects of two different hypocaloric diets on glucagon-like peptide 1 in obese adults, relation with insulin response after weight loss. *J Diabetes Complications*. 2009 Jul-Aug; 23(4): 239-243. Epub 2008 Apr 16.

PubMed ID: 18413175

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compare the effects of two diets on weight loss, circulating GLP-1 levels and the relation with insulin response after weight loss.

Inclusion Criteria:

Not described.

Exclusion Criteria:

- Active infectious disease
- History of cardiovascular disease or stroke during the previous 36 months
- Total cholesterol greater than 300mg/dL
- Triglycerides greater than 400mg/dL
- Blood pressure greater than 140/90mmHg
- Fasting plasma glucose greater than 110mg/dL
- Use of sulphonilurea, thiazolidinedionas, insulin, glucorticoids, angiotensin receptor blocker and angiotensin-converting enzyme inhibitors.

Description of Study Protocol:

Recruitment

Not described.

Design

Randomized controlled trial.

Dietary Intake/Dietary Assessment Methodology

Assessment of subjects' dietary intake was done using three-day food records, including two weekdays and one weekend day.

Blinding Used

Not applicable.

Intervention

Subjects were randomly assigned to one of two diets for three months:

- Low-carbohydrate (CHO): 1,507kcal per day, 38% CHO, 26% protein and 36% fat
- Low-fat: 1,500kcal per day, 52% CHO, 20% protein and 27% fat.

Statistical Analysis

- Sample size was calculated to detect differences over 5% of weight loss with 90% power and 5% significance (N=50)
- The distribution of variables was analyzed with the Kolmogorov-Smirnov test
- Quantitative variables with normal distribution were analyzed with a two-tailed, paired and unpaired Student's T-tests
- Non-parametric variables were analyzed with the Mann-Whitney U test and Wilcoxon tests
- Qualitative variables were analyzed with a chi-square tests with Yates correction as necessary
- Pearson and Spearman tests were used to assess correlation analysis
- A multivariate regression model was used to study the dependent variables adjusted by age and sex
- A P-value less than 0.05 was considered statistically significant.

Data Collection Summary:

Timing of Measurements

Not described.

Dependent Variables

- Weight, waist and hip circumferences were measured by study personnel
- Fat mass and fat-free mass was determined using bioimpedance
- Blood pressure was measured by study personnel
- Basal glucose, insulin, homeostasis model assessment (HOMA) for insulin sensitivity, total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides and active glucagon-like peptide 1 (GLP-1) blood levels were measured.

Independent Variables

Diet group, either low-CHO or low-fat.

Control Variables

- Age
- Sex.

Description of Actual Data Sample:

- *Initial N:* N=118 (33 men, 85 women)
- *Attrition (final N):* N=118
  - 52 subjects in the low-CHO diet group
  - 66 subjects in the low-fat diet group
- *Age:* 45.6±16.5 years
- *Ethnicity:* Not described
- *Other relevant demographics:* Not applicable
- *Anthropometrics:* BMI =35.4±5.7kg/m^2. The diet groups did not differ on any measured anthropometrics at baseline
- *Location:* Spain.

Summary of Results:

Changes in Anthropometric Variables and Blood Pressure

There were no significant differences between diet groups in any of the measured anthropometric variables. (*P<0.05 in each group from baseline compared to three months).

	Group 1		Group 2	
Characteristics	**Baseline**	**Three months**	**Baseline**	**Three months**
BMI (kg/m^2)	35.2±6.6	33.9±6.6*	35.9±7.3	34.3±6.9*
Weight (kg)	93.8±20.1	90.4±19.7*	91.5±20.4	87.5±10.1*
Fat-free mass (kg)	55.3±15.7	53.1±15*	49.4±14	48.2±13.3*
Fat mass (kg)	38.5±13	36.5±23.6*	40.2±10.9	37.2±10.1*
Waist circumference	107.6±13.5	105.8±13.4*	107.2±13	100.2±13.9*
Waist-to-hip ratio	0.90±0.1	0.89±0.09	0.92±0.1	0.89±0.1
Systolic BP (mmHg)	139±18	124±13*	142±16	126±16*
Diastolic BP (mmHg)	85.8±7	81.1±7.4	80.7±6.8	79.2±12.8

Classical Cardiovascular Risk Factors

- A significant improvement in both groups was detected in glucose, insulin, HOMA, total cholesterol, LDL-cholesterol and triglyceride levels
- In the low-CHO group, GLP-1 levels did not change after dietary treatment (9.4±3.3 vs. 9.9±3.1ng/ml). In the low-fat group, GLP-1 levels decreased significantly (8.4%) (9.2±3.3 vs. 8.7±3.1ng/ml; P<0.05).

Author Conclusion:

A hypocaloric, low-fat diet decreased GLP-1 levels with a direct correlation with insulin levels. However, subjects on a hypocaloric, low-CHO diet did not change GLP-1 levels.

Reviewer Comments:

Details regarding the timing of assessment of independent and dependent variables is not described.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	No
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes

	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
	3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
	3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
	3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**		Yes
	4.1.	Were follow-up methods described and the same for all groups?	Yes
	4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
	4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
	4.4.	Were reasons for withdrawals similar across groups?	Yes
	4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**		Yes
	5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
	5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
	5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
	5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
	5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A

6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**		Yes
	6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	No
	6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
	6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
	6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
	6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
	6.6.	Were extra or unplanned treatments described?	No
	6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
	6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**		Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	???
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		N/A
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes

	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	No
10.	**Is bias due to study's funding or sponsorship unlikely?**		???
	10.1.	Were sources of funding and investigators' affiliations described?	???
	10.2.	Was the study free from apparent conflict of interest?	???